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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,981	10/31/2003	Sheryl E. Siegel	200.1162US	8850

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,981	SIEGEL, SHERYL E.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,46-56 and 60* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,5,11,12 and 47-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6-10,13-22,46,56 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response to Election/Restriction dated 12/19/07.

Election/Restrictions

Applicant's election without traverse of group I, claims 1-22, 46-56 and 60, and from group I subgroup b., related to claims 3, 6-10, 13-22, 46, 56 and 60 in the reply filed on 12/19/07 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a method of identifying a pharmaceutical composition comprising imparting a scent to a formulation where the scent is undetectable to a human. However the claim does not indicate exactly how the scent would be undetectable. It is unclear if the undetectable nature of the scent is from proximity to the source or from a concentration at the source formulation. Certainly if a drug and its accompanying scent is separated by location from a human olfactory it would be undetectable. Likewise if the concentration of the scent at the source were sufficiently low, it would be undetectable to most humans, through some humans might have increase olfactory abilities not accounted for. Clarification on this limitation is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6-9, 13-16, 19-21 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuwa et al (USPN 5,238,915 hereafter '915). The claims are drawn to a method of identifying a drug comprising imparting a scent onto a pharmaceutical formulation.

The '915 patent teaches a method of imparting a scent to a drug formulation (abstract). The scents are derived from natural oils and plant extracts (col. 2, lin. 5-60). The scents are also provided by chemical sources such as aldehyde or citral sources (col. 3, lin. 5-20). These scents are used singly or in combination (col. 3, lin. 23-25). The aromatics are entrapped in cyclodextrins in powder or granular forms (col. 5, lin. 10-25). The aromatics have a synergistic relationship wit their respective active agents are used for identification such as a narcotic aromatic (col. 6, lin. 16-29). Regarding the delectability of the scents by a human or non human olfactory device, it is the position of the Examiner that such limitations are met inherently by the formulations and method of application of the '915 patent. Since the scent like all other senses is relative to the user. What is undetectable to one human may not be undetectable to another user. Also as indicted above, proximity to the source of the scent can also affect the detectability of the scent by a user. As such if the products of the '915 patent are removed from the immediate proximity of the user the scents would not be detectable by a human. For these reasons the claims are anticipated by the '915 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 6-10, 13-22, 46, 56 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Fuwa et al (USPN 5,238,915 hereafter '915). The claims are drawn to methods of identifying a drug comprising applying a scent to a container by placing a scented pharmaceutical in the container.

As stated above the '915 patent discloses methods of identifying a drug formulation by an associated scent even when undetectable by a human olfactory device by imparting a scent onto the drug formulation. Although the reference is silent to a specific container for the drug formulation, it would obviously be contained in some sort of safe stable container. Since the scented pharmaceutical would be used for aromatherapy or identification the scent would be in sufficient supply to leach or absorb into any surroundings including a closed container. The methods of the instant claims indicate that container is scented by simply placing the scented

pharmaceutical dosage forms into a container. The dosage forms of the '915 can be powders, tablets, capsules or granules, meaning they would require a basic plastic container for transportation and storage. By simply storing the finished dosage forms of the '915 patent, the methods steps are completed since the scented dosages forms are placed into a container, effectively imparting a scent to the container. These methods steps would have been obvious to one of ordinary skill in the art.

With these things in mind it would have been obvious to follow the teachings and suggestions of the '915 patent to package and contain the scented dosage forms thereby imparting a scent to the container. These normal packaging and storage steps would have been obvious to one of ordinary skill in the art and would have resulted in a stable dosage form with enhanced identification properties.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cummings et al (USPN 6,153,220) discloses scented dosage forms. Lodder (USPN 4,893,253) discloses a method of identifying cracked, damaged or abnormal dosage forms via infra-red spectral analysis.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618